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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/530,333	08/18/2005	Cerli Rocha Gattass	B1204/20003	9667

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EXAMINER

LAO, MARIALOUISA

ART UNIT	PAPER NUMBER
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1621

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/23/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No. 10/530,333	Applicant(s) GATTASS ET AL.	
	Examiner MLouisa Lao, Ph.D.	Art Unit 1621	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

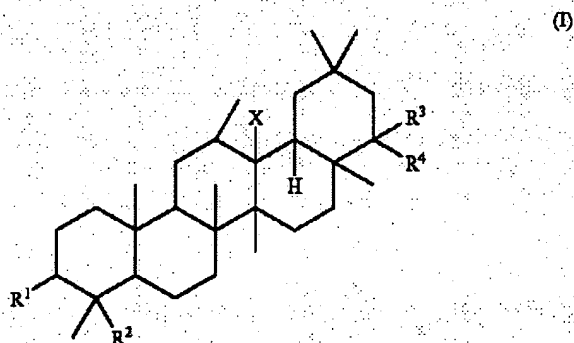
Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

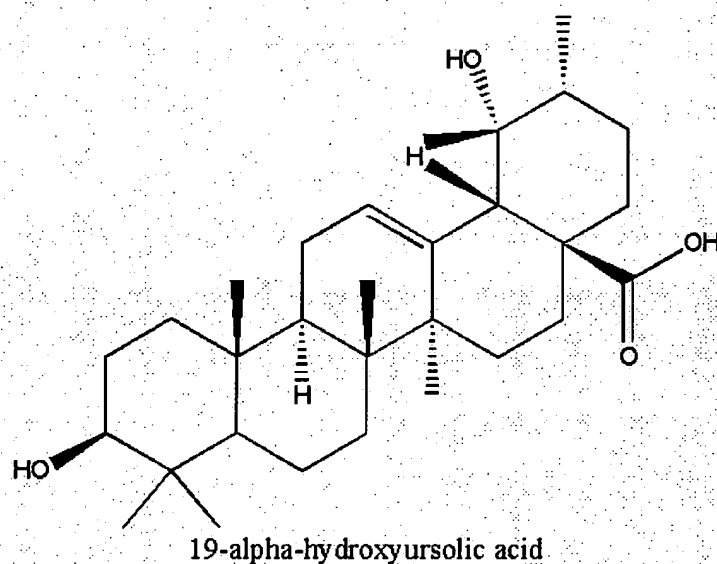
(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1-3 are rejected under 35 U.S.C. 102(e) as being anticipated by Sasaki et al. (USPatent 7153979, USPat'979).
3. The instant claim is directed to “an isolated, purified or synthetic compound selected from the group consisting of pomolic acid, isomers of pomolic acid and derivatives thereof, wherein the compound is effective to treat multidrug resistant tumors.”
4. USPat'979 teaches in column 51 lines 17-54 continuing to column 52 lines 1-54 a triterpene derivative with delineated definitions of the substituent moieties, as shown below:



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The pomolic acid or 19 α -hydroxyursolic acid and its derivatives of the instant claims' recitation would fall under structures taught by USPat'979, as being equivalent, since the structure of pomolic acid is as shown below:



Further, by the applicants' own admission (see specification page 12 lines 16-17), pomolic acid is a molecule derived from plants and well known *[sic]* in the literature.

Albeit USPat'979 is silent as to the efficacy of the compounds of the triterpene of formula (I) towards multidrug resistant tumors, it is well settled that a prior art reference may anticipate when the claim limitations not expressly found in that reference are nonetheless inherent in it. "Under the principle of inherency, if the prior art necessarily functions in accordance with, or includes, the claimed limitations it anticipates." *MEHL/Biophile Int'l Corp. V. Miltraum*, 192 F.3d 1362, 1365, 52 USPQ2d 1303, 1305.

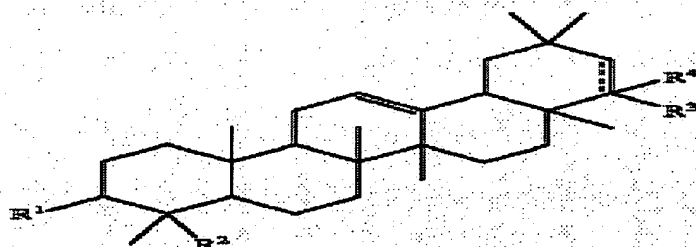
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5. Claims 1-7 are rejected under 35 U.S.C. 102(b) as being anticipated by Sasaki et al. (USPatent 6306862, USPat '862).

6. The instant claims are directed to the pharmaceutical composition comprising an effective amount of at least one compound of claim 1 and at least one pharmaceutically acceptable vehicle, where claim 1 recites "an isolated, purified or synthetic compound selected from the group consisting of pomolic acid, isomers of pomolic acid and derivatives thereof, wherein the compound is effective to treat multidrug resistant tumors."

7. USPat'862 teaches a pharmaceutical composition comprising a triterpene compound, as recited:

A pharmaceutical composition for treating a hepatic disorder, comprising a triterpene derivative represented by the formula (I) or a pharmaceutically acceptable salt thereof is disclosed:



with definitions as delineated in the claims, see column 41 lines 65-67 continuing to columns 42-48 lines 1-67 throughout.

As shown earlier, the pomolic acid would fall under the structures of the compounds used in the compositions as taught by USPat'862. Thus, it is clear that USPat'862 anticipates the instant claims.

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8. Claims 8-9 are rejected under 35 U.S.C. 102(e) as being anticipated by Burman et al. (USPatent 6656970, USPat'970).

9. The instant claims are directed to a method to prepare a pharmaceutical composition, said method comprising solubilizing at least one compound selected from the group consisting of pomolic acid...and the at least one compound is 10mg/ml to 1000mg/ml.

10. USPat'970 in column 10 lines 66-67 continuing to column 11 lines 1-10 and column 12 lines 7-8 teaches a method for increasing the solubility of triterpene derivatives comprising dissolving the triterpene... in an organic solvent and further comprising adding a diluting fluid, where said fluid (see column 10 lines 59-65) is selected *inter alia* from normal saline, where the concentration of the triterpene compound is at 22 mg/ml (see column 10 lines 35-38). Thus, clearly USPat '970 anticipates the instant claims.

11. Claims 10-11 are rejected under 35 U.S.C. 102(e) as being anticipated by Gutterman et al. (USPGPub2006/0148732, USPGPub'732).

12. The instant method claims are directed towards treatment comprising administration... of at least one compound selected from the group consisting of pomolic acid, isomers of pomolic acid and derivatives thereof, where the mode of administration is systemic or oral .

13. USPGPub'732 teaches the a method of inhibiting comprising modes of administering, *inter alia*, systemic or oral (see page 100 claims 49-50), engaging the use of a composition comprising a triterpene moiety (see pages 97-98, claims 3 and 7-11). Herein, USPGPub'732 anticipates the instant claims.

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Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MLouisa Lao, Ph.D. whose telephone number is 571-272-9930. The examiner can normally be reached on 8:30am to 5:30pm Mondays to Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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MLouisa Lao, Ph.D.
Examiner
Art Unit 1621


For THURMAN PAGE,
SUPERVISORY PATENT EXAMINER
GAU1621